

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
(ATLANTA DIVISION)**

**UNITED STATES OF AMERICA,
ex rel. SALDIVAR**

:

Plaintiff,

:

v.

:

Civil Action No. 1:10-cv-01614-AT

**FRESENIUS MEDICAL CARE
HOLDINGS, INC.**

:

Defendant.

...oOo...

**PLAINTIFF/RELATOR CHESTER SALDIVAR'S
MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL
PRODUCTION OF ATTORNEY CLIENT PRIVILEGED
DOCUMENTS AND TESTIMONY**

Plaintiff /Relator Chester Saldivar hereby respectfully requests that the Court order the Defendant to produce attorney client privileged documents and testimony in accordance with the Eleventh Circuit's holding in *Cox v. Administrator U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1419 (11th Cir. 1994). In *Cox*, the Court held that parties waive the attorney client privilege when they assert as a defense their good faith reliance upon a belief that their conduct was legal, which is the essence of Fresenius' various defenses to this case.

STATEMENT OF FACTS

Throughout this litigation, Fresenius has consistently taken the position that it cannot be held liable for fraud because the Company “has always understood that no rule forbade its conduct” and that, therefore, “Fresenius did not have fraudulent intent as a matter of law.” Fresenius’ Brief In Opposition to Relator’s Motion For Summary Judgment and In Support of Its [Defendant’s] Motion For Summary Judgment at p. 2 (“Def. Brf. at ____.”) (Document No. 107). Fresenius further argues that it is entitled to summary judgment because its “interpretation of the [Medicare] rules was reasonable.” *Id.* at p. 32. Finally, Fresenius argues that it cannot be held liable because the government knew about and approved its overfill billings. The “government knowledge inference” that Fresenius seeks to invoke does not apply if the Defendant independently knew that its conduct violated the law. *U.S. ex rel Burlbaw v. Orenduff*, 548 F.3d 931, 953 (10th Cir. 2008) . The inference, like the defense of good faith compliance with the law, requires a full examination of the Defendant’s actual knowledge about whether its actions conformed to the law.¹

¹ Briefly, the government knowledge inference arises when the government knows of the facts underlying allegedly false claims and approves those claims prior to presentment. *Burlbaw*, 548 F.3d at 953.

In addition to Fresenius' judicial admissions that it will defend this case based upon its good faith compliance with the law, Ronald Castle, Fresenius' Deputy Counsel for International Litigation, gave deposition testimony, without objection, that the Company understood that overfill billing was "lawful and entirely proper" and that "there was nothing to prohibit it" in the statute or regulations. September 24, 2012 Deposition of Ronald L. Castle, Dep., 51:14-19, 52:20-24. (Excerpts from Mr. Castle's deposition are attached to this Motion as Exhibit 1). This testimony not only constitutes another assertion of Fresenius' defense of good faith compliance with the law, but it is also an implicit waiver of the attorney-client privilege with respect to the issues before the Court.

Further on the issue of waiver, the Relator served its Second Request for Production of Documents on the Defendant in August, 2012. Those requests specifically sought, *inter alia*, documents that reflected Fresenius' understanding of how overfill was treated under the Average Sales Price methodology of reimbursement. Fresenius responded to those RFDs on September 17, 2012. Significantly, Fresenius did not object to the production of documents responsive to those requests on the basis of privilege. Instead, Fresenius simply replied that it had produced or would produce all documents responsive to the request.

Fresenius' exact response to the Relator's Second RFD, as relevant here, was as follows:

Request No. 1. All documents referring to the method for calculating the Average Sales Price for dialysis drugs.

RESPONSE: Fresenius has produced documents responsive to this request, which include Fresenius' copies of OIG work plans and OIG reports.

Request No. 2. All documents referring to how overfill in dialysis drug vials is treated in the calculation of ASP for Epogen and/or Zemplar.

RESPONSE: See Response to Request for Production No. 1.

(Fresenius' Response to the Relator's Second Request for Production of Documents are attached hereto as Exhibit 2.)

Fresenius demonstrably did not produce all documents relevant to these requests on or about September 17, 2012. One glaring omission was Fresenius' failure to produce documents relating to its own calculations of ASP for Venofer, an ESRD drug that Fresenius acquired in 2008, a fact that undersigned counsel learned during the first stay of discovery. On August 13, 2013, while the stay of discovery was still in place, the Relator filed a motion to lift the stay of discovery to compel production of documents relating to Fresenius' ASP calculations for Venofer. (Document No. 139). The Court denied that motion the following day, without awaiting a response from Fresenius. After the stay of discovery was lifted

on or about October 1, 2013, the Relator requested production of documents from the Defendant. The first production of documents relating to Venofer was made on October 24, 2013. As noted during the parties' telephone call with the Court on January 7, 2014, the Defendant's production of documents relating to Venofer is finally complete, which makes this motion timely.

Despite the fact that Fresenius did not assert an objection to requests for documents relating to the calculation of ASP on the basis of the attorney client privilege, Fresenius has in fact claimed attorney client privilege with respect to a very large number of documents that appear to reflect its internal understanding of how ASP is calculated. The Defendant has yet to produce its final privilege log, but the most recent log, produced on November 25, 2013 lists lists more than two dozen documents that reflect attorney client privileged discussions about calculations of ASP and overfill. (That privilege log is attached to this Motion as Exhibit 3. For the Court's ease of reference, those specific entries relating to ASP discussions have been highlighted.)

The Defendant's October 31, 2013 privilege log shows that Fresenius has also extensively claimed attorney client privilege regarding documents that discuss the changes in Medicare reimbursement brought by the Medicare Modernization

Act of 2003, including the change to ASP reimbursement. For example, according to the privilege log, FRESINIUS- CS-PRIV-3438-3539 is a October, 2004 document entitled “redacted email regarding impact of change in reimbursement rules and attached spreadsheet.” Additionally, FRESINIUS- CS-PRIV- 3748-3764 and 3991-4004 reflect discussions of ASP “language,” including documents at FRESINIUS- CS-PRIV-3991-3998 dated September 23, 2004 that reflect an “emergency conference call at 10 a.m. EST this morning to resolve ASP positions!” These documents clearly reflect Fresenius privileged internal discussion regarding the ASP reimbursement methodology, and may include discussions of whether overfill is included in those calculations and is billable.

With respect to Fresenius’ privileged internal discussions of whether overfill billing is completely legal and proper as Fresenius asserts, the privilege log notes *inter alia* discussion of “attorney advice regarding use of overfill with Trailblazer.” A number of entries, from FRESINIUS-CS-PRIV 3011- 3024 reflect Fresenius’ internal discussions about comments on the 2010 rulemaking by CMS that iterated the Agency’s prohibition on billing for overfill. Certainly, evidence of what Fresenius actually believed about whether overfill was included in calculations of ASP and whether overfill billing was lawful would be found in

these internal discussions (The October 31, 2013 privilege log is attached to this Motion as Exhibit 4, with specific entries that appear to reflect internal discussions relating to the issues raised by this motion highlighted for the Court's ease of reference.)

The parties have conferred in an attempt to resolve this issue without litigation. On November 26, 2013 undersigned counsel for the Relator wrote a detailed letter to Mr. Bennett, Fresenius' lead counsel, setting forth the Relator's position in detail, including citations to *Cox*. Mr. Bennett wrote back on December 18, 2013, with the Defendant's position on the issue. Shortly after receiving and reviewing Mr. Bennett's letter, on December 20, 2013, undersigned counsel emailed him saying that the Relator disagreed with his legal analysis and asking if further efforts to resolve the issue would be fruitful. The parties agreed that no further discussions would be helpful.

The facts recited above show clearly that Fresenius has waived the attorney client privilege with respect to its legal understanding of how ESRD drugs are reimbursed by Medicare under the MMA. Based upon the case law cited below, the Court should order Fresenius to produce privileged documents that reflect those legal opinions.

ARGUMENT

I. **FRESENIUS HAS WAIVED THE ATTORNEY CLIENT PRIVILEGE UNDER ELEVENTH CIRCUIT LAW BY ASSERTING A DEFENSE OF GOOD FAITH COMPLIANCE WITH THE LAW.**

The law is clear in the Eleventh Circuit and elsewhere that a Defendant waives the attorney client privilege when it “injects into the case an issue that in fairness requires an examination of otherwise protected communications.” *Cox v. Administrator U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1419 (11th Cir. 1994). In *Cox*, the Eleventh Circuit considered whether U.S. Steel (“USX”) had waived the attorney client privilege by asserting that it believed its revised personnel policies were completely lawful, in the face of accusations by union members that the Company had changed its leave-of-absence policy to influence union officials by increasing their pension rights during labor negotiations. The Eleventh Circuit noted that “[a]lthough USX denied any intent to assert a defense of advice of counsel or to rely on any privileged attorney-client communications in its defense, . . . ‘USX’s defense . . . necessarily implicates all of the information at its disposal when it made the decision to change the leave-of-absence policy’” *Id.* at 1418.

The Eleventh Circuit affirmed the district court’s holding that USX had

waived the attorney client privilege by asserting this defense, noting that “it would be inequitable to allow USX to present evidence tending to show it intended to comply with the law, while allowing it to cloak in privilege those documents tending to show it might have known its actions did not conform to the law.” *Id.*

The Eleventh Circuit also pointed out that it was USX’s “affirmative . . . [assertion] that it believed that its change in pension fund policy was legal” that “injected the issue of its knowledge of the law into the case and thereby waived the attorney client privilege.” *Id.* at 1419. According to the Court, USX could have simply denied intent without affirmatively asserting good faith, and preserved its privilege. *Id.* See also *U.S. v. Bilzerian*, 926 F.2d 1285,1292 (2d Cir. 1991)(defendant’s testimony that he thought his actions were legal put his knowledge of the law and the basis for his understanding of what the law required in issue and conversations with counsel regarding the legality of his schemes were directly relevant).

Similarly, in a case nearly identical to the one before the Court, Exxon asserted a defense of “good faith compliance with governmental regulations,” in a suit by the government to recoup oil overcharges. *U.S. v. Exxon Corp.*, 94 F.R.D. 246, 247 (D.D.C. 1981). The Court “rejected the defendant’s argument that its

good faith defense only involved communications between Exxon and the government, holding instead that Exxon's "internal statements should also reveal whether Exxon honestly believed that it acted in good faith." *Id.* The Court ultimately concluded that "any documents pertinent to Exxon's defense of good faith are discoverable." *E.g. United States v. Mackey*, 2012 WL 3260462 at *4 (N.D. Ga. 2012)(if privilege existed, it would be waived by assertion of good faith defense to charges that defendant defrauded investors); *Carpenter v. Mohawk*, 2007 WL 5971741 at *12 (N.D. Ga. 2007) (Defendant's assertion that its attorney's interview of the Plaintiff was solely designed to determine whether Plaintiff had violated the law rather than to determine if he had reported violations of the law by the Defendant to the authorities required review of privileged communications). This case law applies squarely to the defenses that Fresenius has asserted here that it acted in "good faith compliance" with the law and regulations.

Fresenius has also asserted that it relied in good faith upon the government's purported approval of overfill billing. The reliance upon the so-called "government knowledge inference" also places Fresenius' understanding of the law directly at issue. The government knowledge inference may apply where a

defendant can show that “the government knows and approves of the facts underlying an allegedly false claim prior to presentment.” *U.S. ex rel Burlbaw v. Orenduff*, 548 F.3d at 952 . Because that inference operates to negate scienter, it is never available where the Defendant also knew that its claims were false. As the Tenth Circuit noted in *Burlbaw*, “[t]he proper focus of the scienter inquiry under Section 3729(a) must always rest on the defendant’s knowledge of whether the claim is false, a ‘knowledge’ which may certainly exist even when a government agency misinterprets its own regulations and chooses - with full comprehension of the facts - to pay a false claim.” *Id.* at 953(collecting cases).

The government knowledge inference thus directly implicates the disclosure of information, including attorney client information, that sheds light on the defendant’s independent understanding of the law and whether its actions complied with that law. *Burlbaw*, 548 F.3d at 953(even when a defendant makes full disclosures to and receives specific government approval, the defendant may still be held liable under the FCA if it independently knew its conduct was wrong). The case law is also clear that to invoke the inference, the defendant must have made a full disclosure of its legal position to the government. *See U.S. v. Newport News Shipbuilding Co.*, 276 F.Supp.2d 539, 564 (E.D. Va. 2003) (defendant’s

failure to disclose its interpretation of a regulation and *verify its accuracy* with the government is sufficient to satisfy the reckless disregard standard of the FCA). In order to determine whether Fresenius made a full disclosure, the Plaintiff and the Court must be able to determine the Defendant's actual understanding of the law..

Fresenius's choice to raise these particular defenses – that its conduct was completely legal and that it relied upon government approval of its overfill billing – rather than to simply deny that it had intent to defraud under the False Claims Act – brings this case squarely within the holding of *Cox*. The Relator is entitled to production of all documents, including attorney client privilege documents, that reflect Fresenius' actual understanding of the legality of billing for overfill.

As the Eleventh Circuit noted in *Cox*, “[a] defendant may not use the privilege to prejudice his opponents’ case or to disclose some selected communications for self-serving purposes.” 17 F.3d at 1417. The Court held that “such selective disclosure for tactical purposes waives the privilege.” *Id.* Fresenius’ tactical disclosures of attorney client privilege material through Mr. Castle’s testimony and its assertion of specific defenses in this case, without a full waiver, fundamentally prejudices the Relator’s case. One can just imagine the reaction of a jury to testimony by Fresenius’ Deputy General Counsel that he

believed that his client's action were "completely legal" without any corresponding evidence from the Relator about what the Company actually knew about what the law required.

The Eleventh Circuit has made clear that this cannot be permitted to happen, through its holding in *Cox*. This Court is obligated to follow that case law. The Relator is entitled to have all documents, attorney client privilege and otherwise, that reflect Fresenius internal discussions about whether overfill billing is legal, but particularly those that reflect Fresenius' understanding that the exclusion of overfill from ASP calculations meant that the provider may not bill for overfill, in keeping with the Court's prior ruling that claims for overfill are false as a matter of law. *U.S. ex rel. Saldivar v. Fresenius*, No. 1:10-CV-1614-AT (N.D. Ga) slip op. at. 34-35.

II. FRESENIUS HAS WAIVED THE ATTORNEY CLIENT PRIVILEGE BY FAILING TO OBJECT TO DOCUMENT REQUESTS AND TESTIMONY THAT ELICITED INFORMATION PROTECTED BY THE PRIVILEGE.

Furthermore, independent from the assertion by Fresenius of particular "good faith" defenses, Mr. Castle's deposition testimony, along with the Defendant's failure to object to the Plaintiff's RFD on the grounds of attorney

client privilege, waived the privilege with respect to confidential communications that shed light on Fresenius' purported understanding of whether its conduct was lawful. The law is clear that parties can waive the privilege expressly or by implication. "[A]ny voluntary disclosure by the holder of such privilege is inconsistent with the confidential relationship and thus waives the privilege."

Sperling v. City of Kennesaw Police Dept., 202 F.R.D. 325, 328 (N.D. Ga. 2001).

"A defendant may not use the privilege to prejudice his opponent's case or to disclose some selected communications for self-serving purposes." *Cox*, 17 F.3d at 1417. Such "selective disclosure for tactical purposes waives the privilege." *Id.*

As the Court noted in *Jackson v. Deen*, 2013 WL 3863889 (S.D. Ga. 2013), in considering the very issue before the Court -- that is whether the testimony of the Defendant's attorney waived the privilege -- "it is axiomatic, however, that the express intention to retain the attorney client privilege does not serve to proactively negate any action that effectively waives that privilege." *Id.* at *5. In *Deen*, the Court found that the Defendant intended to rely upon its attorney's deposition testimony, while trying to shield from view any other communications with him about the same subject matter. The Court held that the attorney client privilege had been waived. *Id.* at *4. Thus, "when a party defends its actions by

disclosing attorney-client communication, it waives the attorney client privilege as to all such communications regarding the same subject matter.” *Outside The Box Innovations LLC v. Travel Caddy, Inc.*, 455 F.Supp.2d 1374, 1376 (N.D. Ga. 2006). Importantly, “it is not necessary for a party to raise an affirmative defense . . . in order to waive the privilege.” “Any injection of factual issues covered by the privilege waives the privilege.” *Cox*, 3 F.3d at 1417. And, where a party has waived the privilege, the “waiver extends to all other communications relating to the same subject matter.” *Bell South Advertising & Publishing Corp. v. American Business Lists, Inc.*, 1992 U.S. Dist. Lexis, 17679, *22, 24. Fresenius’ conduct of this case, as set forth above, demonstrate that the Defendant has waived the attorney client privilege.

CONCLUSION

For all of the foregoing reasons, the Plaintiff/Relator respectfully requests that the Court order production of all attorney client privileged documents and testimony that reflects Fresenius’ understanding about how ASP was calculated and whether overfill billing was permitted by the Medicare statute and implementing regulations.

Respectfully submitted, this 8th day of January, 2014.

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CERTIFICATE OF COUNSEL REGARDING DISCOVERY DISPUTE

Pursuant to Fed. R. Civ. P. 37(a)(2)(B), the undersigned hereby certifies that she has, in good faith, conferred with counsel for Defendant in an effort to secure the information and material described herein without court action.

This 8th day of January , 2014.

/s/ Jamie M. Bennett

CERTIFICATE OF COUNSEL REGARDING FONT SIZE

Pursuant to Local Rule 7.1(D), the undersigned hereby certifies that this pleading has been prepared with a Times New Roman 14 point font, as approved by the Court in Local Rule 5.1(B).

This 8th day of January , 2014.

/s/ Jamie M. Bennett

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of January, 2014, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which sent notification of the filing to all counsel of record.

/s/ Jamie M. Bennett